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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/716,453 | 11/20/2003 | Piero Melloni | 2818-176 | 6639 |

23117 7590 12/30/2004
NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

OH, TAYLOR V

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,453

Applicant(s)

MELLONI ET AL.

Examiner

Taylor Victor Oh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-43 and 45 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Final Rejection

The Status of Claims

Claims 37-45 are pending.

Claims 1-36 have been canceled.

Claims 37-43 and 45 have been rejected.

Claim 44 has been objected.

Claim Objections

Claim 45 is objected to because of the following informalities:

in the amendment, there is no marking of (New) in claim 45. This is improper because applicants did not follow recent rule makings in USPTO.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 42-43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 39, 42-43 and 45, the phrase " a previous preparation reaction " is recited. The expression is vague and indefinite because there is no explanation as to

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what is meant by "a previous preparation reaction" in the specification. Therefore, an appropriate correction is required.

Claim Rejections-35 USC 103

1. Applicants' argument filed 10/18/04 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 37-43 and 45 under 35 U.S.C. 103(a) as being unpatentable over Frick et al (Synthesis, J. of Syn. Org. Chem. p.621-623) is maintained for the reasons of the record on 7/22/04.

The rejection of Claims 37-43 and 45 under 35 U.S.C. 103(a) as being unpatentable over Frick et al (Synthesis, J. of Syn. Org. Chem. p.621-623) is maintained for the reasons of the record on 7/22/04.

Applicants' Argument

2. Applicants argue the following issues:
 1. The Frick et al has failed to teach the use of NaCl ;
 2. The claimed aspartic acid and HCl concentrations are disclosed;
 3. the precipitation of the end product by cooling the reaction mixture is not mentioned.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first and fourth arguments, the Examiner has noted applicants' argument. However, the Frick et al does teach the preparation of (S)-chlorosuccinic acid by converting (S)-aspartic acid with the treatment of sodium nitrite in hydrochloric acid (see page 621 ,lines 36-38); during which NaCl is formed in-situ by the reaction of sodium nitrite with hydrochloric acid. From this, it follows that the prior art does teach the use of NaCl indirectly.

Therefore, the Frick et al is relevant to the claimed invention.

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, in the example 10 (bromosuccinic acid) (see page 622, right col. first paragraph) , the concentration of aspartic acid can be estimated from 90 ml of water introduced in the reaction and 50.8 g of aspartic acid ; the HCl concentration can be also estimated indirectly from the concentration of H₂SO₄ (2.5 M,

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990 ml) since the prior art teaches that both HCl and H₂SO₄ can be employed in the reaction process.

Third, regarding the third argument, the prior art is silent about the precipitation of the reaction product. However, from the example 10 (bromosuccinic acid) (see page 622, right col. first paragraph), it is possible to precipitate the reaction product upon the consideration of the cooling temperature of -5° C during the isolating step. Furthermore, it is well-known in the art that either one of the extraction and the precipitation can be used in the isolation step.

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to use the precipitation technique as an alternative to the extraction in order to isolate the desired product in the process because the skilled artisan in the art would expect such a modification to be effective under the condition of cooling temperature of -5° C.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TV Oh
12/22/04

Cecilia J. Tsang
Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600